## II. REMARKS

**Introductory Comments**

Claims 1-15 were examined in the Office Action under reply and stand variously rejected under (1) 35 U.S.C. §112, second paragraph (claim 15); (2) 35 U.S.C. §112, first paragraph (claims 1-15); and (2) 35 U.S.C. §103(a) (claims 1-15). These grounds of rejection are believed to be overcome by this response and are otherwise traversed for reasons discussed in detail below.

**Overview of the Above Amendments**

The specification has been amended to insert the priority information listed on the front page of PCT Publication No. WO 2005/016380 (appended) from which this application derives.

Claims 2-5, 9-12, 16-25 and 33-39 have been canceled. Claim 1 has been amended to incorporate recitations from canceled claims 3 and 5 and now recites that the IL-2 is des-alanyl-1, serine 125 human interleukin-2 and the anti-CD52 antibody is Alemtuzumab. Claim 6 has been amended to read in dependent format and claims 7 and 8 have been amended for antecedent basis purposes. Claim 15 has been amended to correct typographical errors and also now recites the range of 1100 μg to 2565 μg. Support for these amendments can be found in the original claims, as well as throughout the specification at, e.g., page 7, lines1-4.

The foregoing amendments are made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications containing the unamended claims.

**35 U.S.C. §112, Second Paragraph**

Claim 15 was rejected under 35 U.S.C. §112, second paragraph as indefinite. The Examiner requests clarification regarding the dosage units used. As explained above, claim 15 has been amended to correct obvious typographical errors and also now recites the range specified at page 7, lines 1-4 of the application. Accordingly, this basis for rejection has been

overcome and withdrawal thereof is respectfully requested.

**35 U.S.C. §112, First Paragraph**

Claims 1-15 were rejected under 35 U.S.C. §112, first paragraph as nonenabled. In particular, the Examiner argues the claims are not enabled for using a "fragment" of an anti-CD52 antibody, Alemtuzumab and an interleukin-2 or variant thereof. The claims have been amended to eliminate the reference to a fragment. Thus, this basis for rejection has been overcome and withdrawal thereof is respectfully requested.

**35 U.S.C. §103(a)**

Claims 1, 2, 4-9 and 11-13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rieger et al., *Leuk. Lymphoma* (2004) 45:345-349 ("Rieger"); in view of Kay et al., *Nouv. Rev. Fr. Hematol.* (1988) 30:475-478 ("Kay"), and further in view of Denis-Mize et al., *J. Immunother.* (2003) 26:S43 ("Denis-Mize"), and Dmoszynska et al., *Leuk. Lymphoma* (1999) 34:335-340 ("Dmoszynska").

Claims 2, 3, 9 and 10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rieger, in view of Kay, Denis-Mize, Dmoszynska and U.S. Patent No. 4,518,584 to Mark et al.

Claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Rieger, in view of Kay, Denis-Mize, Dmoszynska and Ayanlar-Batuman et al., *Blood* (1986) 67:279-284.

Claim 15 was rejected under 35 U.S.C. §103(a) as being unpatentable over Rieger, in view of Kay, Denis-Mize, Dmoszynska and Safar et al., *Immunopharmacol.* (2000) 49:419-423.

Applicants note that each of the rejections above relies on Rieger as the primary reference. However, Rieger post-dates applicants' priority date of July 30, 2003. (See, the front page of PCT Publication No. WO 2005/016380 from which this U.S. national phase application derives). Applicants have also inserted this claim for priority into the specification. Accordingly, Rieger is not prior art to the present claims. Since all of the combinations above rely on Rieger, all bases of rejection have been overcome. Withdrawal thereof is respectfully requested.

## III. CONCLUSION

Applicants respectfully submit that the claims are now in condition for allowance and request early notification to that effect. The Examiner is encouraged to contact the undersigned if the Examiner notes any further matters which might be resolved by a telephone interview.

Respectfully submitted,

Date: 9/11/09

By: _____
Roberta L. Robins
Registration No. 33,208

ROBINS & PASTERNAK LLP
1731 Embarcadero Road, Suite 230
Palo Alto, CA 94303
Telephone: 650-493-3400
Facsimile: 650-493-3440

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(71) Applicant (*for all designated States except US*): **CHIRON CORPORATION** [US/US]; Intellectual Property, R338, Emeryville, CA 94662-8097, P.O. Box 8097 (US).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **HURST, Deborah** [US/US]; C/o Chiron Corporation, Intellectual PropertyR338, 4560 Horton Street, Emeryville, CA 94608-2916 (US). **OSTERBORG, Anders** [SE/SE]; Karolinska Hospital, S-171 76 Stockholm (SE). **QUADT, Cornelia** [DE/US]; C/o Chiron Corporation, Intellectual PropertyR338, 4560 Horton Street, Emeryville, CA 94608-2916 (US). **WOLIN, Maurice, J.** [US/US]; C/o Chiron Corporation, Intellectual PropertyR338, 4560 Horton Street, Emeryville, CA 94608-2916 (US). **MILAN, Sandra** [US/US]; C/o Chiron Corporation, Intellectual PropertyR338, 4560 Horton Street, Emeryville, CA 94608-2916 (US).

(74) Agents: **CHIRON CORPORATION** et al.; Intellectual Property, R338, P.O. Box 8097, Emeryville, CA 94662-8097 (US).

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(54) Title: METHODS OF THERAPY FOR CHRONIC LYMPHOCYTIC LEUKEMIA

(57) Abstract: Methods for treating a human with chronic lymphocytic leukemia using a combination of an interleukin-2 and an anti-CD52 antibody are provided. These therapeutic agents are administered as two separate pharmaceutical compositions, one containing an IL-2, the other containing an anti-CD2 antibody, according to a dosing regiment. Administering of these two therapeutic agents together results in a positive therapeutic response that is improved with respect to that observed with anti-CD52 antibody alone.

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